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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 08/828,323 | 03/28/97 | O'DONNELL | M 19603/10213 |

18M2/0804

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| ART UNIT | PAPER NUMBER |
|---|---|
| 1814 | 4 |

DATE MAILED: 08/04/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) 1 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

**Application Papers**

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ The drawing(s) filed on _____ _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☒ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

– SEE OFFICE ACTION ON THE FOLLOWING PAGES –



* U.S GPO: 1996-410-238/

*****NOTE*****: The instant application does not comply with current Seuqnce Rules. It is noted that no Computer Readable Form appears with the application. Compliance is REQUIRED. To simplify matters, it is suggested that applicant submit a letter requesting the use of the most recent Sequence Listing of the immediate parent application, stating that they are identical, with no new matter, etc., as cited in the Sequence Rules 1.821.

***Claim Rejections - 35 USC § 112***

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to the subunits of DNA polymerase III holoenzyme from Escherichia coli, does not reasonably provide enablement for such from other sources. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to produce the invention commensurate in scope with these c The specification details and enables the isolation of both the genes and proteins of the claimed 5 subunits of the polymerase holoenzyme from E. coli. The specification does not, however, demonstrate nor teach of such subunits from any other source. Other such polymerase III systems are known in the art, for example, from Salmonella typhimurium, which are not contemplated by the instant specification. It would require an undue amount of experimentation for one skilled in the art to attempt to isolate the claimed subunits from any other source, as there is no guidance provided for such a procedure in other organisms, where to search for such a complex, and it would be unpredictable if the other organisms containing the polymerase III holoenzyme would contain all 5 of the subunits claimed. Thus, the claim is not enabled by the instant specification for the subunits other than from E. coli, considering the breadth of the claim, the amount of experimentation unduly necessary, the scarcity of guidance and/or working examples, and the unpredictable nature of the art.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Takase et al.

Takase et al. disclose the rlpA gene from E. coli encoding a lipoprotein of 36 kDa. This sequence matches that of the sequence encoding the claimed delta (δ) subunit gene, and has been isolated and expressed in the reference. Thus, the reference anticipates the invention of claim 1 as it relates to the delta subunit gene.

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Stirling et al.

Stirling et al. teach of the xerB gene from E. coli. This gene sequence matches that of the sequence encoding the claimed chi (χ) subunit, and has been isolated and expressed in the reference. Thus, Stirling et al. anticipates the invention of claim 1 as it relates to the chi subunit gene.

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Yoshikawa et al.

Yoshikawa et al. disclose the rimI gene from E. coli. This gene sequence matches that of the sequence encoding the claimed psi (ψ) subunit, and has been isolated and expressed in the reference. Thus, Yoshikawa et al. anticipates the invention of claim 1 as it relates to the psi subunit gene.

NOTE: Regarding claim 1, the genes encoding subunits theta (θ) and delta prime (δ') are free of the prior art of record. They are novel, as they do not appear in the prior art, and it would not have been obvious to obtain the gene encoding the proteins from the

information supplied in the prior art. No usable sequence information existed for the proteins or DNA at the time the invention was made, and thus they are deemed patentable over the prior art.

NOTE: All references cited herein may be found as cited and relied upon in parent application serial number 08/279,058.

***Double Patenting***

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the allowed claims of copending Application No. 08/279,058. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim encompasses the individual claimed inventions of the copending case.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

NO CLAIM IS ALLOWED.

This is a Continuation of applicant's earlier Application No. 08/279,058. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the

advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith D. Hendricks, whose telephone number is (703)308-2959.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at (703) 308-4216. The fax phone number for this Group is (703) 305-4227. Unofficial papers and proposed amendments may be faxed directly to (703)305-7401.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**robert.wax@uspto.gov**].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

KEITH D. HENDRICKS
PRIMARY EXAMINER
GROUP 1800

kdh
August 3, 1997